

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

**DEBBIE ANN BOLTON, surviving child of
Decedent, Ruth Clara Summers,**

Plaintiff,

v.

**GALLATIN CENTER FOR
REHABILITATION & HEALING, LLC,**

Defendant.

Civil Action No. 3:20-cv-00683

**CHIEF JUDGE CRENSHAW
MAGISTRATE JUDGE HOLMES**

STATEMENT OF INTEREST OF THE UNITED STATES

The United States respectfully submits this Statement of Interest, pursuant to 28 U.S.C. § 517, to address the preemptive effect of the Public Readiness and Emergency Preparedness Act (the “PREP Act” or “Act”) , 42 U.S.C.A. §§ 247d-6d, 247d-6e (West 2020), should this Court find it applicable in this case.

COVID-19 presents an unprecedented global challenge, requiring a whole-of-nation response. To encourage the efficient development and deployment of medical countermeasures during such emergencies, in the PREP Act, Congress limited liability for losses related to the administration or use of countermeasures, like diagnostics and treatments, that are specified by the Secretary of Health and Human Services by declaration.

As explained below, the PREP Act completely preempts claims relating to the administration or use of covered countermeasures with respect to a public health emergency, as declared by the Secretary. Therefore, cases that include such claims necessarily include federal questions and, therefore, are removable. The United States is not a party to this litigation and takes no position as to whether the Act applies to any particular claim alleged in Plaintiff’s Complaint in this case.

However, the United States has an interest in having the PREP Act applied uniformly across jurisdictions and across public health emergencies. The United States therefore respectfully submits this Statement of Interest to assist the Court in resolving the pending motion to remand should the Court determine that the allegations in Plaintiff's Complaint fall within the ambit of the Act.

BACKGROUND

Congress has established procedures “to prepare for, protect against, respond to, recover from, or mitigate” national emergencies, 6 U.S.C. § 314, and has provided that “[t]he Secretary of Health and Human Services shall lead all Federal public health and medical response to” such emergencies, 42 U.S.C. § 300hh. The PREP Act is a crucial part of the comprehensive federal effort to promote the “[r]apid distribution and administration of medical countermeasures” in response to a public health emergency, *id.* § 300hh-1(b)(2). The statute vests the Secretary with the authority to determine the existence or credible future risk of a public health emergency, and to issue a declaration recommending administration of specified countermeasures. *See id.* § 247d-6d(b).

Successful distribution and administration of these countermeasures, including diagnostic tests, therapeutics, and vaccines, depends on the cooperation of private-sector partners, as well as state and local officials across the nation. To encourage such cooperation and to maximize the efficiency of the national response to public health emergencies, Congress provided broad immunity to “covered persons,” *id.* § 247d-6d(i)(2), for claims relating to the administration to or use by an individual of countermeasures that aid in that response. *Id.* § 247d-6d(a) (including “claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure”).

PREP Act immunity is sweeping, applying “to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure,

including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.” *Id.* § 247d-6d(a)(2)(B). In other words, all damages actions for conduct relating to covered persons’ administration of countermeasures specified in a PREP Act declaration are preempted.

In place of tort remedies, Congress created the Covered Countermeasure Process Fund to compensate eligible individuals for serious physical injuries or deaths from pandemic, epidemic, or security countermeasures identified in declarations issued by the Secretary. *See id.* § 247d–6e. The PREP Act also creates, as “the sole exception to the immunity from suit and liability,” an “exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct” of that person. *Id.* § 247d-6d(d)(1); *see also id.* § 247d-6d(c), (e)(1).

In response to the COVID-19 pandemic, the Secretary of Health and Human Services has issued a Declaration recommending the use of various “covered countermeasures.” *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21,012 (Apr. 15, 2020), and 85 Fed. Reg. 35,100 (June 8, 2020), and 85 Fed. Reg. 52,136 (Aug. 24, 2020), and 85 Fed. Reg. 79,190 (Dec. 4, 2020), *available at* <https://www.phe.gov/Preparedness/legal/prepact/Pages/4-PREP-Act.aspx>.

The Declaration defines “covered countermeasures” broadly to include “all qualified pandemic and epidemic products under the PREP Act” (*e.g.*, “any antiviral, any drug, any biologic, any diagnostic, any other device . . . to diagnose, mitigate, prevent, treat, or cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom,” that is approved or authorized for emergency use by the Food and Drug Administration, among other products). *Id.* It interprets

“administration” thereof to mean “physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.” 85 Fed. Reg. at 79,197. The Declaration also states that “[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act and this Declaration’s liability protections.” *Id.* In particular, “[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute ‘relating to . . . the administration to . . . an individual’ under 42 U.S.C. 247d-6d.” *Id.* For example, “where there is only one dose of a COVID-19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional,” if the “healthcare professional administers the one dose to the person who is more vulnerable to COVID-19,” “the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population ‘relat[es] to . . . the administration to’ the person in a vulnerable population” for PREP Act purposes. *Id.* Additionally, the latest amendment to the Declaration states that the Declaration “must be construed in accordance with the Advisory Opinions of the Office of the General Counsel” and incorporates those Advisory Opinions as part of the Declaration. *Id.* at 79,194-95.¹

¹ See, e.g., Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act (Apr. 17, 2020, as modified on May 19, 2020), available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf>; Advisory Opinion 20-02 (May 19, 2020), available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>; Advisory Opinion 20-03 (Oct. 22, 2020, as modified on Oct. 23, 2020), available at <https://www.hhs.gov/guidance/sites/>

STATEMENT

The Supreme Court first recognized the doctrine of complete preemption as a basis for federal-question removal jurisdiction under 28 U.S.C. § 1441(a) over 50 years ago, identifying the Labor Management Relations Act as a complete-preemption statute. *Avco Corp. v. Aero Lodge No. 735, Intern. Ass’n of Machinists & Aerospace Workers*, 390 U.S. 557, 559 (1968). Since then, the Court has extended the doctrine to two other statutes, the Employee Retirement Income Security Act (“ERISA”) and the National Bank Act. *See Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 7–11 (2003) (National Bank Act completely preempts state law); *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 67 (1987) (ERISA completely preempts state law); *see also Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004) (same). Notably, the Second Circuit has applied the doctrine to the Air Transportation Safety and System Stability Act (“ATSSSA”), which is structurally similar to the PREP Act. *In re WTC Disaster Site*, 414 F.3d 352, 375 (2d Cir. 2005). And a state appellate court in New York has determined that the PREP Act is a complete-preemption statute, in response to litigation stemming from the H1N1 flu pandemic. *Parker v. St. Lawrence Cty. Pub. Health Dep’t*, 102 A.D.3d 140, 143–45 (N.Y. App. Div. 2012) (dismissing state-law complaint for lack of jurisdiction).

Complete preemption is jurisdictional in nature: by establishing an exclusive federal cause of action, a statute may permit removal via federal question jurisdiction even of a complaint pleading only state-law causes of action. A complete-preemption statute reflects Congress’s intent to “so completely pre-empt a particular area that any civil complaint raising [a] select group of claims is

default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf; Advisory Opinion 20-04 (Oct. 22, 2020, as modified on Oct. 23, 2020), *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf; *see also* Advisory Opinion 21-01 (Jan. 8, 2021), Dkt. No. 32 at 3–7.

necessarily federal.” *Metro. Life Ins. Co.*, 481 U.S. at 63–64 (emphasis added). In other words, the existence of such a powerfully preemptive federal cause of action causes the invalid assertion of a state cause of action to raise a federal question, because “a claim which comes within the scope of that [federal] cause of action, even if pleaded in terms of state law, is in reality based on federal law.” *Beneficial Nat’l Bank*, 539 at 8; *see Metro. Life Ins. Co.*, 481 U.S. at 65–66 (explaining that complete-preemption provisions “convert[] an ordinary state common law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule”).

“The proper inquiry focuses on whether Congress intended the federal cause of action to be exclusive rather than on whether Congress intended that the cause of action be removable.” *Beneficial Nat’l Bank*, 539 U.S. at 10 n.5.² It does not focus on the nature of any remedy the federal court or law may or may not provide. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 391 n.4 (1987) (“The nature of the relief available after jurisdiction attaches is, of course, different from the question whether there is jurisdiction to adjudicate the controversy” (quoting *Avco Corp.*, 390 U.S. at 561)). Instead, the complaint, any statutes on which the claims are based, and any other relevant materials (*e.g.*, plan documents in an ERISA case) determine whether the plaintiff’s cause of action falls “within the scope” of a completely preemptive statute. *See Aetna Health Inc.*, 542 U.S. at 211. It does not matter whether the complaint expressly raises a federal claim or cites the completely preemptive federal statute—what matters is whether the complaint’s causes of action fall within the federal statute’s scope (and are therefore necessarily federal and grounds for removal). *See id.*

² *But see Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553 (6th Cir. 2005) (seemingly requiring that “the federal statutory language demonstrates that Congress has manifested a clear intent that claims not only be preempted under the federal law, but also that they be removable”). Although *Palkow*’s language post-dates *Beneficial National Bank*, it cannot have disturbed the Supreme Court’s rejection of any requirement to demonstrate Congressional intent to make certain claims removable for complete preemption to apply. 539 U.S. at 10 n.5.

Thus, complete preemption is fundamentally unlike other, substantive preemption doctrines (e.g., express, implied, field, conflict, impossibility, or obstacle preemption, which do not in and of themselves give rise to removability. And complete preemption sidesteps the general rule that a federal defense (like other, substantive types of preemption) does not provide grounds for removal to federal court. *See Metro. Life Ins. Co.*, 481 U.S. at 63, 66; *Husvar v. Rapoport*, 430 F.3d 777, 781–82 (6th Cir. 2005); *see also Marin Gen. Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 944–45 (9th Cir. 2009) (explaining the different types of preemption). “The rationale is that in such situations the federal statutory laws ‘supersede both the substantive and remedial provision of state’ law creating a strong form of federal preemption—presumably because of the additional need for a strong form of national uniformity implied by Congress when it made federal court jurisdiction exclusive after broadly preempting state law.” *Ritchie v. Williams*, 395 F.3d 283, 286 (6th Cir. 2005) (quoting *Beneficial Nat’l Bank*, 539 U.S. at 11) (finding certain state-law copyright claims completely preempted under the Copyright Act).

The PREP Act is just such a complete-preemption statute with respect to the administration or use of covered countermeasures by covered persons under a declaration by the Secretary. Whenever a claim “for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure” is brought against a covered person and a declaration under subsection (b) has been issued, that claim is necessarily federal and removable. 42 U.S.C. § 247d–6d(a).

Two key provisions of the PREP Act operate together to demonstrate its completely preemptive nature: the immunity provision and the exclusive alternative remedy provision.

First, the Act provides for immunity “under Federal and *State law* with respect to *all* claims for loss caused by, arising out of, relating to, or resulting from the administration” of

countermeasures specified by the Secretary. *Id.* § 247d-6d(a)(1) (emphasis added). “Loss” is broadly defined to “mean[] *any* type of loss, including . . . physical, mental, or emotional injury, illness, disability, or condition,” and “fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring.” *Id.* § 247d-6d(a)(2) (emphasis added). *See generally Parker*, 102 A.D.3d at 143 (quoting subsection (a) as demonstrating completely preemptive intent).

Second, the Act establishes, as the “sole exception” to subsection (a)’s immunity grant, “an exclusive Federal cause of action” for claims of willful misconduct resulting in death or serious physical injury. 42 U.S.C. § 247d-6d(d)(1). It also establishes an exclusive venue for such excepted claims: “only” before a three-judge panel of the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1), (e)(5). Even such excepted claimants, though, must first apply for benefits through the federal Covered Countermeasure Process Fund, which permits individuals to make no-fault benefits claims for certain injuries. *See id.* § 247d-6e(d)(1). *See generally Parker*, 102 A.D.3d at 144 (quoting subsection (d) as demonstrating completely preemptive intent).

Together, these provisions show that Congress determined—in the limited context addressed by subsection (a) involving claims relating to the administration or use of covered countermeasures with respect to a public health emergency, as declared by the Secretary—that tort actions are not necessary or appropriate to deter tortious conduct, intentional or negligent, except as provided in the “exclusive” federal cause of action created by the statute itself. *See* 42 U.S.C. § 247d-6d(d)(1); *see also id.* § 247d-6d(c)(1)(B) (The Act “establish[es] a standard for liability that is more stringent than a standard of negligence in any form or recklessness.”); *Parker*, 102 A.D.3d at 143–44 (“Considering the breadth of the preemption clause together with the sweeping language of the statute’s immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the

administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary . . .”).

Moreover, reading these PREP Act provisions as completely preemptive accords with the reasons Congress enacted the law. An effective response to national health emergencies depends on the prompt and willing cooperation of private partners. Thus, the Act broadly immunizes covered persons from claims relating to their administration of specified countermeasures, while specifying exclusive alternative remedies for certain claims. Congress determined that the deterrent and compensatory effects of tort liability, which might be salutary in other contexts, would undermine the nation’s ability to protect itself from epidemics and pandemics. This balance forms one key part of Congress’s comprehensive scheme for developing and sustaining a national pandemic response, including the “[r]apid distribution and administration of medical countermeasures.” 42 U.S.C. § 300hh-1(b)(2).

Two cases further support a completely preemptive reading of these PREP Act provisions in applicable cases.

In re WTC Disaster Site found in provisions of the ATSSSA “an intent to displace state-law remedies entirely” for damages claims arising out of the hijacking of planes on September 11, 2001. 414 F.3d at 375. Those provisions included “an exclusive federal remedy” in the form of a federal cause of action with exclusive venue in the United States District Court for the Southern District of New York. *Id.* The Second Circuit relied heavily on the exclusive alternative cause of action in finding that complete preemption applied, while also finding relevant the ATSSSA’s compensation fund for victims. *Id.* at 373, 375. Congress passed the PREP Act, *see* Pub. L. No. 109–148, 119 Stat. 2680 (Dec. 30, 2005), just months after the *In re WTC Disaster Site* decision, *see* 414 F.3d at 352. And it included analogous provisions: substituting an exclusive federal claim for state law claims,

directing that such claims be filed in just one district court, and creating a victim compensation fund. With a proper focus on “whether Congress intended the federal cause of action to be exclusive,” *Beneficial Nat’l Bank*, 539 U.S. at 10 n.5, it becomes clear that the PREP Act provisions discussed above “bespeak an intent to displace state-law remedies entirely for such damages claims” as fall within their ambit, *In re WTC Disaster Site*, 414 F.3d at 375.

Similarly, in *Beneficial National Bank*, the Supreme Court found the National Bank Act to be completely preemptive for reasons equally applicable here: That statute provides “the exclusive cause of action” for state usury claims against a national bank, 539 U.S. at 9, much like the PREP Act does for state claims against covered persons relating to the administration of covered countermeasures. The PREP Act “form[s] a system of regulations” for the nation’s response to public health emergencies, displacing any state law that differs from or conflicts with it. *Id.* at 10 (quoting *Farmers’ & Mechanics’ Nat’l Bank v. Dearing*, 91 U.S. 29, 32–33 (1875)). The PREP Act thus “completely defines what constitutes” a cognizable claim against covered persons relating to the administration of covered countermeasures. *Id.* (quoting *Evans v. Nat’l Bank of Savannah*, 251 U.S. 108, 114 (1919)). And the “same federal interest that protected national banks from . . . state taxation” and interference supports similar protection for those vital to the nation’s pandemic response. *Id.* at 11 (recognizing “the special nature of federally chartered banks”). “Because [the PREP Act] provide[s] the exclusive cause of action for such claims, there is, in short, no such thing as a state-law claim” of loss against a covered person relating to the administration of a covered countermeasure. *Id.*

A recent and oft-cited case to the contrary, *Maglioli v. Andover Subacute Rehabilitation Center*, No. 20-6605, 2020 WL 4671091 (D.N.J. 2020), *appeal docketed*, No. 20-2834 (3d Cir. Sept. 10, 2020), appears to have interpreted the complete preemption doctrine and the PREP Act

imprecisely. *Maglioli* focuses almost entirely on subsection (b)(8), an express conflict-preemption provision. *See id.* at *7, *9.³ It relegates subsection (a) to mere “background.” *Id.* at *6. This approach gets it backwards: subsections (a) and (d) operate together to demonstrate that Congress intended an exclusive federal cause of action for “claims for loss” within (a)’s ambit, whereas (b)(8) expressly preempts (without completely preempting, in a jurisdictional sense) *other* laws, legal requirements, and therefore claims beyond (a)’s ambit. Thus, the court’s holding “that the PREP Act does not so occupy the field as to squeeze out state court jurisdiction over what are state-law claims of negligence and require an exclusive federal forum,” *id.* at *11, frames the inquiry incorrectly. Field preemption is a different doctrine than complete preemption and the PREP Act does include a completely preemptive provision, as evidenced by its creation of immunity for a certain class of claims and an exclusive federal forum for exceptions to that immunity. 42 U.S.C. § 247d-6d(a), (d)(1); *see also Parker*, 102 A.D.3d at 143 (citing subsection (b)(8) as demonstrating completely preemptive intent).⁴

Moreover, these and other cases finding that the PREP Act did not completely preempt certain claims should not be read to hold that the PREP Act is *never* completely preemptive. Rather, such cases have typically found that the claims pleaded did not, in the court’s view, arise from the

³ This provision expressly preempts (in the ordinary, non-jurisdictional sense) any state or local law that conflicts with this part of the Act:

no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision . . . or requirement that . . . is different from, or is in conflict with, any requirement applicable under this section [§ 247d-6d] and relates to . . . the administration by qualified persons of the covered countermeasure.

42 U.S.C. § 247d-6d(b)(8).

⁴ This is not to say that the *Maglioli* court got the result there incorrect as well. It may be that the complaint there raised only claims outside subsection (a)’s ambit (*i.e.*, claims that were not subject to complete preemption) such that it was correct to remand that case. In any event, the *Maglioli* court was correct to observe that careful “case by case analysis” is required. 2020 WL 4671091 at *9.

use or administration of a covered countermeasure. *See, e.g., Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, No. 20-CV-1198, 2020 WL 6140474, at *7 (W.D. Pa. Oct. 16, 2020), *appeal docketed*, No. 20-3287 (3d Cir. Nov. 10, 2020) (finding claims outside the purview of the PREP Act); *Martin v. Serrano Post Acute LLC*, No. CV 20-5937 DSF (SKX), 2020 WL 5422949, at *2 (C.D. Cal. Sept. 10, 2020) (finding defendants provided no support for complete preemption argument “other than stating the standard”), *appeal docketed*, No. 20-56067 (9th Cir. Oct. 16, 2020); *Haro v. Kaiser Found. Hosps.*, No. CV 20-6006, 2020 WL 5291014, at *3 (C.D. Cal. Sept. 3, 2020) (“Haro’s minimum wage claim is not causally connected to any of Kaiser’s covered countermeasures.”); *Baskin v. Big Blue Healthcare, Inc.*, No. 2:20-cv-2267, 2020 WL 4815074, at *6 (D. Kan. Aug. 19, 2020) (finding plaintiff’s claim of loss not causally connected or related to the administration or use of covered countermeasures); *Maglioli*, 2020 WL 4671091, at *10 (finding social distancing, quarantining, and other measures not covered countermeasures and therefore not within the scope of the Act). Those cases are limited to their facts, which may or may not be analogous to the Complaint in this case, and should not be read to hold that the PREP Act is not a completely preemptive statute *per se*.

Indeed, as discussed above, these PREP Act “provisions supersede both the substantive and the remedial provisions of state [tort] laws and create a federal remedy for [certain claims of loss relating to covered countermeasures] that is exclusive, even when a state complainant . . . relies entirely on state law. Because [they] provide the exclusive cause of action for such claims, there is, in short, no such thing as a state-law claim of [loss] against a [covered person in connection with their use or administration of a covered countermeasure].” *Beneficial Nat’l Bank*, 539 U.S. at 11.

CONCLUSION

The United States takes no position on whether the Complaint includes any claim that falls within the ambit of 42 U.S.C. § 247d-6d(a), and thus necessarily takes no position as to whether any particular claim in this case is completely preempted by the Act. If such a claim has been pled, however, it is necessarily federal and the Complaint is removable because of the completely preemptive nature of that PREP Act provision.⁵

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⁵ In doing so, “considerable weight should be accorded to” the Department of Health and Human Services’ construction of the PREP Act (as evidenced in the Declaration and Advisory Opinions incorporated into it cited above), because the Act is “a statutory scheme [HHS] is entrusted to administer.” *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001) (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984)).

Dated: January 19, 2021.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Statement of Interest of the United States was filed on January 19, 2021 with the Court's Electronic Case Filing System (CM/ECF), and service was made upon all persons registered in this case, including:

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